



Allogene Therapeutics is a biotechnology company with a mission to catalyze the next revolution in cancer treatment through the development of allogeneic chimeric antigen receptor T-cell (CAR T) therapy directed at blood cancers and solid tumors. Founded and led by former Kite Pharma executives who bring unrivaled clinical development acumen in cell therapy, Allogene is well-positioned to further the potential of allogeneic cell therapy for patients.

Allogeneic CAR T therapies are engineered from cells of healthy donors and stored for “off-the-shelf” use in patients. This approach eliminates the need to create personalized therapy from a patient’s own cells, simplifies manufacturing, and reduces the time patients must wait for CAR T treatment. The Allogene portfolio includes 16 pre-clinical T cell therapy assets and UCART19, an allogeneic CAR T therapy currently in Phase 1 development for the treatment of acute lymphoblastic leukemia (ALL). Through its notable partnerships, Allogene leverages pioneering technology platforms, including TALEN® gene editing technology, to progress its portfolio of immuno-oncology therapies. Allogene, with headquarters in San Francisco, California, is a Two River portfolio company formed with one of the largest Series A financings in biotechnology from an investment consortium which includes TPG, Vida Ventures, BellCo Capital, the University of California Office of the Chief Investment Officer, and Pfizer. For more information, please visit www.allogene.com, follow @AllogeneTx on Twitter and LinkedIn.

Position: Head of Biostatistics

Location: San Francisco, CA

Job Description:

Allogene is seeking a Head of Biostatistics to ensure systems, capabilities and resources are in place that optimize the design, conduct, analysis and interpretation of clinical and nonclinical data for each program. The ideal candidate for this role is an individual who is excited to take on new challenges in a fast-paced and dynamic start-up environment.

Responsibilities:

- Responsible for writing statistical methodology section of the protocol, including sample size calculation.
- Responsible for writing statistical analysis plans (including mockup TLFs) for individual studies and ISS/ISE.
- Plan regulatory filings and ensure a timely submission with efficiency and accuracy in regulatory filing activities.
- Direct the activities of internal and external statistical programmers, to ensure the intended analyses are performed, and analysis data sets and their specifications are in place, following STDM standards.
- Review and comment on eCRFs, annotated eCRFs, edit checks documents and other clinical data management related documents.
- Participate in operations meetings and address issues related to biometrics.
- Support and participate in the preparation of study reports, regulatory submissions, and annual IND safety update reports.
- Perform ad hoc analysis and data validation.
- Develop and contribute to Biometrics SOPs and standard working documents meeting regulatory requirements throughout biometrics processes including IWRS/EDC, STDM, statistical programming for TLFs, and data reporting.
- Communicate clinical trial data internally. Ensure that the interpretation of data obtained from Allogene trials, from trials conducted by Allogene’s collaboration partners, CROs and competitive data is accurate, scientifically sound and credible.

Requirements:

- B.S. in computer sciences, statistics or biostatistics required. Advanced degree preferred.
- Minimum of 10 years of data management and clinical programming experience in the pharmaceutical or biotechnology industry, at least 5 years of Oncology experience preferred.
- Extensive knowledge of clinical research methodology and regulatory requirements as they related to trial design and analysis is required; experience in oncology is required.
- Good knowledge of ICH, FDA, and GCP regulations and guidelines; strong well-rounded technical skill, SAS, SDTM, and CDISC.
- Has scientific background and understanding of clinical trials, clinical development operations and regulatory compliance.
- Extensive experience negotiating successfully with health authorities.
- Capability to provide statistical leadership to cross-functional teams and the ability to both communicate and influence the biostatistical perspective to diverse audience across research and development



- Strong statistical skills with application in at least one of the following areas: target discovery/validation, lead compound development, computational chemistry/biology, translational research (including imaging and biomarker development/validation), clinical enabler studies, and early clinical drug development.
- Ability to work in a fast-paced, start-up environment.
- Strong attention to detail with the ability to multi-task and handle multiple responsibilities simultaneously.
- Excellent organizational skills and an ability to prioritize effectively to deliver results within reasonably established timelines.
- Ability to work independently and as part of a team.
- Strong interpersonal skills including verbal and written communication are essential in this collaborative work environment.
- Candidates must be authorized to work in the U.S.

As an equal opportunity employer, Allogene Inc. is committed to a diverse workforce. Employment decisions regarding recruitment and selection will be made without discrimination based on race, color, religion, national origin, gender, age, sexual orientation, physical or mental disability, genetic information or characteristic, gender identity and expression, veteran status, or other non-job related characteristics or other prohibited grounds specified in applicable federal, state and local laws. In order to ensure reasonable accommodation for individuals protected by Section 503 of the Rehabilitation Act of 1973, the Vietnam Era Veterans' Readjustment Act of 1974, and Title I of the Americans with Disabilities Act of 1990, applicants who require accommodation in the job application process may contact careers@allogene.com for assistance.

For more information about equal employment opportunity protections, please view the ['EEO is the Law'](#) poster.